



# Health Effects & Wine: The FDA Should Regulate the Health Effects on Wine Labels

## Citation

Health Effects & Wine: The FDA Should Regulate the Health Effects on Wine Labels (2002 Third Year Paper)

## Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8889443>

## Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

## Share Your Story

The Harvard community has made this article openly available.  
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

# **Health Effects & Wine: The FDA Should Regulate the Health Effects on Wine Labels**

Sara Levison Golden

Class of 2002  
Food & Drug Law Course Paper  
March 2002

## Abstract

In 1976, the District Court of the Western District of Kentucky, in *Brown-Forman Distillers Corp. v. Matthews*, found that alcoholic beverages were exempt from the Food & Drug Administration labeling requirements. Since then the Bureau of Alcohol, Tobacco, and Firearms has had exclusive jurisdiction over the labeling of alcoholic beverages. As a result of the recent findings on the health effects of alcoholic beverages, in particular wine, it is necessary to revisit that 1976 decision. The FDA currently allows health claims to appear on the labels of food as long as there is significant scientific agreement on the evidence to support the claim. These standards establish a workable rule to allow health claims to appear on food and drink. These guidelines should be expanded to cover wine labels.

## I. Introduction

Recent studies suggest that wine might be more than just the perfect accompaniment to an elegant dinner; it may also have important health benefits. Wine is being shown to reduce coronary heart disease. These benefits are being leaked to the American public through news reports and articles in newspapers and magazines. Currently, wine labels cannot include the reported health benefits of this fine grape beverage. This paper will argue that the wine consumer should be able to read the benefits directly on the label. More importantly, the consumer should be able to trust the labels to provide accurate and reliable information. Currently, alcohol labels are governed by the Bureau of Alcohol Tobacco and Firearms, which enforces the Federal Alcohol Administration Act (FAAA). The FAAA covers all alcoholic beverages having seven percent alcohol, those beverages with lower levels and cooking wine are regulated by the FDA. The BATF does not have the expertise to properly regulate health effects on alcohol labels; consequently the FDA, which has the proper framework to effectively do this, should regulate this. In 1990, the NLEA was passed giving FDA the power to regulate health claims on food labels. The NLEA sets up guidelines for the scientific standard of the research necessary to justify the health claim. These guidelines or something similar should be applied to alcoholic beverage labels. Since the FDA has the experience of regulating health claims and evaluating

scientific research it is appropriate for this agency to regulate wine and all alcohol.

This paper will explore the reasons why the FDA should regulate the health claims on wine labels. First, it will be necessary to understand the history of the BATF's jurisdiction over alcoholic beverages. Next it will be necessary to explore the framework established by the NLEA. Third, it is necessary to evaluate the current research on alcohol and wine. Last, the reasons why the FDA is the most appropriate agency to regulate wine labels will be presented.

## **II. The FDA Can Better Regulate the Health Claims of Wine Labels**

### **A. BATF's Exclusive Control over Wine Labels**

The FDA and BATF shared jurisdiction over alcoholic beverages from 1938 until 1976. During this time the labeling was reserved to the BATF and the FDA only continued to retain control over adulteration in alcoholic beverages. In order to understand BATF's current role it is first necessary to explore the historical root of their jurisdiction and then to delve into the current role that the BATF plays in regulating wine.

In 1935, Congress passed the Federal Alcohol Administration Act, which gave the authority to regulate the labels of alcoholic beverages to the Department of Treasury, who designated the BATF as the enforcement authority.<sup>1</sup> Until 1935 alcohol labels were regulated under the Pure Food and Drug Act of 1906.<sup>2</sup> After thirty years, Congress decided that this was insufficient because it only prohibited falsity and deception.<sup>3</sup> The 1935 Act required that alcohol labels contain the identity and the quantity of the product, the net contents, and alcohol content.<sup>4</sup> When Congress passed the FD&C Act in 1938 they did not limit the definition of food to

---

<sup>1</sup>Brown-Furman Distillers Corp. v. Matthews, 435 F. Supp. 5 (D.C.Ky. 1977).

<sup>2</sup>*Id.* at 7.

<sup>3</sup>*Id.* at 9.

<sup>4</sup>*Id.*

exclude alcoholic beverages and so the debate over the jurisdiction began.<sup>5</sup> The Food Drug and Cosmetic Act of 1938 defines food as “articles used for food or drink for man or other animal.”<sup>6</sup> The BATF clearly has jurisdiction over labels under the 1935 Act, and the FDA believed that they shared jurisdiction with BATF as a result of the 1938 FD&C Act.<sup>7</sup> In 1940, the FDA issued a statement that indicated their position on alcoholic beverages.

While we have indicated that cordials, liqueurs, wine and whiskey are subject to the Act (the FD&C Act), we will continue as in the past to leave to the Federal Alcohol Administration the regulation of the labeling of these alcoholic beverages under the more specific Federal Alcohol Administration Act. . . we expect to continue our policy of not duplicating the work of the Federal Alcohol Administration.<sup>8</sup>

BATF exerted exclusive control over the approval of the labels of alcoholic beverages for thirty-five years. On October 8, 1974, FDA and BATF entered into a Memorandum of Understanding that confirmed BATF’s primary jurisdiction over alcoholic beverage labels.<sup>9</sup> The Memorandum announced that BATF had adopted ingredient regulations that were in agreement with the FDA.<sup>10</sup> After the comment period, BATF withdrew the proposed regulation. BATF cited the following reasons for withdrawing the ingredient labeling proposal: (1) cost to the industry and the consumer, (2) the content of alcohol is extensively regulated, (3) uniqueness of the process of manufacturing alcohol may make an ingredient list misleading to the consumer, (4) hindrance on international trade negotiations, and (5) only a small segment of the public supports ingredient labeling.<sup>11</sup> These reasons indicate that there was strong industry support against ingredient labeling. In response to BATF’s withdrawal, FDA issued a statement that they would be abandoning the memorandum

---

<sup>5</sup>*Id.* at 7.

<sup>6</sup>21 U.S.C.A. §321(f).

<sup>7</sup>*Id.*

<sup>9</sup>*Id.* at 8.

<sup>10</sup>*Id.*

<sup>11</sup>*Id.*

of understanding and that they would begin to enforce ingredient labeling for alcoholic beverages.<sup>12</sup>

In *Brown-Forman Distillers Corp. v. Matthews*,<sup>13</sup> the plaintiffs brought a declaratory judgment that the FDA did not have jurisdiction to regulate the labeling of alcoholic beverages.<sup>14</sup> The plaintiffs in this action were eight distillers, one winemaker, the Distilled Spirits Council of the United States (approximately 95% of all United States distillers), and the National Association of Alcoholic Beverage Importers.<sup>15</sup> Although the industry was successful in getting the BATF to rescind the proposal for ingredient labeling, when the FDA attempted to exert its control and require this labeling the industry responded strongly with this action. When the Court in *Brown-Forman Distillers* considered the issue of jurisdiction they went back to the legislative history of the FD&C Act of 1938 to determine if the word “food” was supposed to include alcoholic beverages. Although there was no discussion directly on point as to how the FD&C Act was to effect the 1935 Act, there was an interesting question that was asked by Congressman Virgil Chapman during the hearings.<sup>16</sup> In this question he made clear that he proposed to amend the bill to “include whiskey and require adequate labeling that would disclose the various ingredients...”<sup>17</sup> The Court properly concluded that this question indicated that Congress did not think that the definition of food, as it was written in the Act, included alcoholic beverages. The House Committee’s report indicated that the definition of food was no more than a clarification of the 1906 Act.<sup>18</sup> It is clear that Congress intended for the BATF to have authority over labeling. The Court next considered the issue of joint jurisdiction finding that Congress intended to place exclusive jurisdiction with the BATF through the 1935 Act.<sup>19</sup> The FD&C Act’s adulteration provisions are the only FDA regulations that still apply to alcoholic beverages.<sup>20</sup> The alcohol industry had

---

<sup>12</sup>*Id.*

<sup>13</sup>435 F.Supp. 5 (W.D. Ky. 1976).

<sup>14</sup>*Id.*

<sup>15</sup>*Id.* at 5, note 1.

<sup>16</sup>*Id.* at 10.

<sup>17</sup>*Id.* at 10.

<sup>18</sup>*Id.* at 9.

<sup>19</sup>*Id.* at 13.

<sup>20</sup>Peter Barton Hutt and Richard A. Merrill, *FOOD AND DRUG LAW: CASES AND MATERIALS*, 2<sup>nd</sup> Ed. 79 (1991).

escaped the threat of ingredient labeling for the time being.

In 1979, the BATF tried once again to propose regulations of ingredient labeling in alcoholic beverages. On June 13, 1980 a final rule was promulgated which required ingredient disclosure on labels of wine, distilled spirits, and malt beverages.<sup>21</sup> This rule had an exception or a way out for alcoholic beverage manufacturers. The manufacturer could elect to make the ingredient label available upon request as long as the label includes the full information of where to obtain the ingredient label.<sup>22</sup> Consumer advocates got ingredient labeling and the industry still had the flexibility to provide a less expensive method of supplying this information. The BATF did require mandatory labeling of FD&C Yellow No. 5 because of the health problems associated with this substance.<sup>23</sup> In preparing for issuing of these new regulations, BATF did considerable research including hiring a private consulting firm to conduct a cost-benefit analysis.<sup>24</sup> The BDM Corporation study emphasized that depending on the assumptions that were used the cost of new labels ranged from \$12 million to \$150 million.<sup>25</sup> In addition, the study reported that adverse effects were not limited to allergic reactions so the health costs that would be saved would be hard to calculate.<sup>26</sup> The study concluded that ingredient labeling would be of no real value to the consumer.<sup>27</sup>

Once again the BATF did not go through with the regulation, on May 4, 1981 the notice was published announcing the intent to rescind the prior regulation.<sup>28</sup> The reasons for this were as follows: (1) increased cost to the consumer and a burden on the industry that was outweighed by the possible benefit, (2) ingredient labeling would not provide significant additional benefits to the consumer.<sup>29</sup> This action resulted

---

<sup>21</sup>Center for Science in Public Interest v. Dept. of Treasury, 573 F. Supp. 1168, 1170 (D.C.D.C. 1983).

<sup>22</sup>*Id.* at 1171.

<sup>23</sup>*Id.*

<sup>24</sup>*Id.*

<sup>25</sup>*Id.*

<sup>26</sup>*Id.*

<sup>27</sup>*Id.* at 1172.

<sup>28</sup>*Id.*

<sup>29</sup>*Id.*

in litigation yet again. The Center for Science in the Public Interest and two individual plaintiffs brought suit claiming that the Department of Treasury (the BATF) had violated Federal Alcohol Administration Act and the Administrative Procedure Act by rescinding the regulation.<sup>30</sup> The wine industry submitted an *amicus curiae* brief in support of the government's rescission.<sup>31</sup> The Court in *Center for Science in Public Interest v. Dept. of Treasury* considered with greater scrutiny the change in policy since this was a rescission of a rule and not rule making. One of the main considerations was whether the reasons given by the BATF for the rescission of the regulation were justified. The rationale which sparks the greatest interest is "ingredient labeling regulations would result in increased costs to consumers and burdens on industry which are not commensurate with the benefits which might flow from the additional label information."<sup>32</sup> Since the industry was given the option to be exempt from the requirements by putting the address on the label with notice that ingredient information could be obtained from the manufacturer, the court found that this was not convincing. The court also found that the Department of Treasury did not provide reasoned explanations for their decisions. What is more interesting than the court's decision, however, is the reliance that the BATF placed on cost-benefit analysis in determining the applicability of such regulations from the beginning. The reliance on cost analysis places value on human life. When it comes to health claims and information, the BATF is easily swayed to side with industry when the costs are significant. Although the consumers "won" in this case, the fact that the alcoholic beverage industry has the ear of BATF means that cost will dictate these decisions and the consumers will lose.

Ingredient labeling is still not present on alcoholic beverages; however, there are a few health-related statements that now appear on labels. The BATF operates under the Federal Alcohol Administration Act. The Act provides the following guidance to the BATF, labels on alcoholic beverages: (1) shall prohibit deception of the consumer in regard to age, manufacturing process, analyses, guarantees, or scientific matters; (2)

---

<sup>30</sup>Center for Science in Public Interest v. Dept. of Treasury, 573 F. Supp. 1168 (D.C.D.C. 1983).

<sup>31</sup>*Id.*

<sup>32</sup>*Id.* at 1176 (quoting 46 Fed. Reg. 55094 (1981)).



provide the consumer with adequate information regarding the identity, quality, and alcohol content of the products; (3) provide an accurate statement regarding blended spirits regarding the use of neutral spirits; (4) prohibit statements that disparage competitor's products or that are false, misleading, obscene or indecent; (5) shall prohibit deception by endorsement or trade name.<sup>33</sup> Congress has since added regulations that specifically address health concerns. The first two warnings that were required to appear on the labels of alcoholic beverages were a result of the Alcoholic Beverage Labeling Act in 1988.<sup>34</sup> Congress decided that the public should be adequately warned about the hazards of alcohol consumption. To avoid creating confusion, Congress decided the language of the warnings.<sup>35</sup>

GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.<sup>36</sup>

In 1993, BATF considered health claims on labels yet again, but this time the positive health effects of alcohol consumption was the issue. BATF addressed this in the first edition of the ATF Compliance Matters. At that time, BATF recognized there was scientific research showing a possible relationship between moderate alcohol consumption and decreased risk of heart disease.<sup>37</sup> The Department of Health and Human Services advised BATF that the benefits did not outweigh the health risks and such information should be carefully considered in any policy on health effects labeling.<sup>38</sup> The BATF announced that it would be in consultation with the FDA to determine the best approach for evaluating the health claims.<sup>39</sup> The BATF intended to

---

<sup>33</sup>27 U.S.C.A. §205.

<sup>34</sup>27 U.S.C.A. §213 et.seq.

<sup>35</sup>ATF Compliance Matters, *Industry Circular: Health Claims in the Labeling and Advertising of Alcoholic Beverages*, <<http://www.atf.treas.gov/pub/alcotob-pub/comp931.htm>> 93-1 (1993).

<sup>37</sup>*Id.* at \*8.

<sup>38</sup>*Id.*

<sup>39</sup>*Id.*

utilize the scientific and public health expertise of the Food and Drug Administration.<sup>40</sup> Currently, the health claims on food are approved under the authority of the Nutrition Labeling and Education Act, which will be discussed in further detail in the following section. In recognition that the FAAA's mandate is only to prevent misleading statements on the labeling of alcoholic beverages and that this is more limited than the mandate of the FD&C Act, the BATF did not feel comfortable blindly adopting the FDA's standard.<sup>41</sup> Instead the BATF proposed to open up the debate for public comment. Although no specific action came out of that 1993 statement, the Treasury did announce approved health related statements in February of 1999.

In 1999, the Department of Treasury announced that approved two statements for wine labels.<sup>42</sup> The two statements are (1) "The proud people who made this wine encourage you to consult your family doctor about the health effects of wine consumption." (2) "To learn the health effects of wine consumption, send for the Federal Government's Dietary Guidelines for Americans, Center for Nutrition Policy and Promotion, USDA, 1120 20<sup>th</sup> Street, NW, Washington, DC 20036."<sup>43</sup> These statements for wine labels had been strongly supported by wine producers.<sup>44</sup> This is the third example of how the industry has convinced BATF to create a policy that favors the industry. To illustrate the pressure of the industry, in 1998, the Robert Mondavi Corporation was convicted for trying to influence the Secretary of Agriculture with gifts.<sup>45</sup> One of the policies that Mondavi hoped to influence was the USDA Dietary Guidelines.<sup>46</sup> Every five years these guidelines are reevaluated, Mondavi hoped that moderate consumption of wine would be included as a health benefit that

---

<sup>40</sup>*Id.* at \*9.

<sup>41</sup>*Id.*

<sup>42</sup>Treasury News *Treasury Announces Actions Concerning Labeling of Alcoholic Beverages*, Feb. 5, 1999 RR -2937.

<sup>43</sup>*Id.*

<sup>44</sup>*Id.*

<sup>45</sup>US v. Robert Mondavi Corporation, (D.C.D.C. 1998)

<sup>46</sup>*Id.*

was worthy of the guidelines.<sup>47</sup> The guidelines now include statement regarding wine consumption. Although that statement is not a direct influence of Mondavi's action, the case does illustrate the lengths the industry will go to for a favorable policy.

The latest development on health claims on alcohol labels came in December of 1999 when the BATF announced that they would hold public hearing on the issue. The latest regulation would allow health claims to appear on alcoholic beverage labels as long as they were "balanced." The BATF wants to ensure that any positive health claims are presented to the consumer along with negative health claims. The concern is that people might come to incorrect conclusions about the use of alcohol. BATF is also concerned that the two statements approved in February for wine labels will not provide the intended benefit to the consumer and might be misleading.

For the past twenty-five years the BATF has had exclusive control over the labels of alcoholic beverages. This brief analysis of some of the policy decisions of the BATF illustrate that the agency is heavily influenced by the industry, which it is supposed to control. On two occasions the BATF attempted to require ingredient labeling. And, on two occasions the BATF rescinded their proposal because of the cost that it would impose on the industry. The current shift in policy in favor of health claims labeling makes BATF subject to extreme scrutiny. The agency is trying to balance the industry interest with the consumer's interest. Within the last ten years the industry influence has changed with the possibility of positive health benefits of moderate consumption. Now that health effects on labels may provide economic benefit, the industry is ready and willing to support this new policy. Once again BATF is attempting to balance these interests as evidenced by the statement that labeling can include positive health effects as long as it presents balanced information regarding the negative effects of alcohol consumption. The BATF does not have the experience or the neutral position to properly evaluate health claims for alcoholic beverages. It is therefore necessary to look to other

---

<sup>47</sup> *Id.*

approaches. The FDA currently evaluates health claims under the Nutrition Labeling and Education Act. This approach will be examined to determine its applicability to this issue.

## **B. The NLEA**

In 1990 Congress passed the Nutrition Labeling and Education Act. The NLEA was revolutionary because for the first time the FDA was allowing health claims on food labels. Previously health claims could not be put on food labels because this type of statement would bring the food within the scope of the drug laws, which require much greater scrutiny. The NLEA was a response to consumer interests, changes in the marketplace, and advances in science.<sup>48</sup> As the advances in science showed the connection between a healthy diet and decreased risk of disease, it was necessary for the FDA to recognize these links. Although the FDA did not issue any new regulations to address these issues in the 1980s, the FDA did relax its policies.<sup>49</sup> Surprisingly, FDA did not take regulatory action against Kellogg's All-Bran® when the label included a statement that fiber could reduce the risk of cancer.<sup>50</sup> In 1990, Congress ended the ambiguousness of their 1980s policy by enacting the NLEA.

The NLEA allows health claims to appear on food labels. The health claim must be preapproved by the FDA through notice and comment rulemaking.<sup>51</sup> In order to obtain approval for a health claim it was necessary to meet a very high scientific standard. The FDA will approve health claims if the totality of the publicly available scientific evidence indicates that there is significant scientific agreement among qualified experts

---

<sup>48</sup>Steven B. Steinborn, Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 Food & Drug L. J. 401, 404 (1999).

<sup>49</sup>*Id.*

<sup>50</sup>*Id.*

<sup>51</sup>*Id.*

that the claim is supported by scientific evidence.<sup>52</sup> In addition, the food may be disqualified if it goes above the specified levels for fat, saturated fat, or sodium.<sup>53</sup> The substance that is the subject of the health claim must be contained in the food at a minimum threshold level and have minimal nutritional value.<sup>54</sup> Lastly, the health claim must identify factors besides the substance in a person's diet that influence the diet-disease relationship.<sup>55</sup>

From 1990-1994 the FDA used the NLEA in an effective manner by approving several health claims and assuring that no misleading claims appeared on food labels. The success of the NLEA was short lived, the Food and Drug Administration Modernization Act of 1997 (FDAMA) ended FDA's authority to require approval of each and every health claim.<sup>56</sup> Manufacturers may now make health claims based on an authoritative statement published by a scientific body of the United States government. The manufacturer must submit the following three things to the FDA: (1) notification to the FDA within 120 days prior to marketing of the food, (2) provide support for the claim with an authoritative statement of a scientific body who has official responsibility for public health or research directly related to human nutrition, and (3) submit balanced literature supporting the claim.<sup>57</sup> Once this information is submitted, the claim is approved unless the FDA issues a regulation prohibiting the claim within 120 days.<sup>58</sup> The FDAMA greatly limits the authority to control the legitimacy of health claims on food that was given to the FDA through the NLEA. Although FDA no longer approves each claim, proponents of FDAMA argue that the claims are still subject to the same requirements as defined by the NLEA.<sup>59</sup> The claim must still meet the significant scientific agreement

---

<sup>52</sup> *Id.*

<sup>53</sup> *Enforcement Policy Statement on Food Advertising*, <<http://www.ftc.gov/bcp/policystmt/ad-food.htm>> \*8 (May 1994).

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> Ilene Ringel Heller, *Functional Foods: Regulatory and Marketing Developments*, 56 Food & Drug L.J. 197, 200 (2001).

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 201.

requirement, the food must contain at least ten percent of the recommended daily allowance of vitamin A, vitamin C, calcium, protein, or fiber, and the food must not have excessive levels of fat, saturated fat, or sodium.<sup>60</sup>

Under these new laws health claims were prohibited on both food and dietary if they were not supported by adequate scientific support. In *Pearson v. Shalala*,<sup>61</sup> the U.S. Court of Appeals heard a challenge to NLEA based on the first amendment rights of the manufacturer of dietary supplements. This was the first challenge to limit the authority of the FDA over health claims. In 1999, the District Court for the District of Columbia limited the power of the FDA and determined that the health claim was not misleading and should be allowed.<sup>62</sup> The plaintiff, a dietary supplement marketer, attempted to gain approval from the FDA for four specific health claims. These claims were (1) “consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers,” (2) “Consumption of fiber may reduce the risk of colorectal cancer,” (3) “Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease,” and (4) “.8 mg of folic acid in a dietary supplement is more effective in reducing risk of neural tube defects than a lower amount in foods in common form.”<sup>63</sup> The FDA determined that all four claims failed to rise to “significant scientific agreement,” and therefore would not be approved for the labels of the dietary supplements.<sup>64</sup> The FDA also refused the plaintiff’s alternative of permitting the claims with a disclaimer such as “The FDA determined that the evidence supporting the claim is inconclusive.”<sup>65</sup>

The plaintiffs in *Pearson v. Shalala* claim that their First Amendment rights have been violated because the FDA has refused to allow the manufacturer to use disclaimers, which would serve the government’s interest and allow the plaintiff freedom of expression.<sup>66</sup> Furthermore, they argue that the FDA has failed

---

<sup>60</sup>*Id.*

<sup>61</sup>164 F.3d 650 (D.C. Cir. 1999).

<sup>62</sup>*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

<sup>63</sup>*Id.* at 652.

<sup>64</sup>*Id.* at 653.

<sup>65</sup>*Id.* at 654.

<sup>66</sup>*Id.*

to adequately define the standard “significant scientific agreement” and such failure is a violation of the plaintiff’s Fifth Amendment right to due process.<sup>67</sup> The First Amendment claim was evaluated based on the commercial speech doctrine. The Court found that truthful advertising is entitled to First Amendment protection. The government argues, however, that because the claims are potentially misleading and the consumer has no way to independently evaluate the claim, the consumer may assume that the government has approved the claim. The Court proceeded to evaluate the government’s argument using the three-part test for commercial speech set out in *Central Hudson*.<sup>68</sup> The first issue is whether the government’s interest is substantial. The Court agreed that “public health and consumer fraud” were two important governmental concerns.<sup>69</sup> The next issue to consider is “whether the regulation directly advances the government interest asserted.”<sup>70</sup> The FDA asserts that barring all health claims that are not FDA approved protects the consumer’s interest.<sup>71</sup> The court is skeptical of this paternalistic attitude. The real problem for the government, however, is meeting the third part of the test, whether the fit between the government’s means and the desired ends are reasonable.<sup>72</sup> The government argues that the commercial speech doctrine does not prefer disclosure over complete censure.<sup>73</sup> The Court does not agree with the government’s position, responding that “disclaimers as constitutionally preferable to outright suppression.”<sup>74</sup> Since the FDA failed to consider whether disclosure would satisfy the government’s interest in protecting the consumer, they have blatantly disregarded a less restrictive method.<sup>75</sup> The case was remanded and the FDA was required to consider whether the disclaimer would sufficiently satisfy the government’s interest.<sup>76</sup> In addition, the FDA

---

<sup>67</sup>*Id.* at 655.

<sup>68</sup>*Id.* at 655.

<sup>69</sup>*Id.* at 656.

<sup>70</sup>*Id.* (quoting *Central Hudson*, 447 U.S. 557, 566 (1980)).

<sup>71</sup>*Id.* at 656.

<sup>72</sup>*Id.*

<sup>73</sup>*Id.* at 657.

<sup>74</sup>*Id.*

<sup>75</sup>*Id.* at 658.

<sup>76</sup>*Id.* at 661.

was required to provide guidance on the meaning of “significant scientific agreement.”<sup>77</sup>

The paternalistic approach to FDA would be replaced with a more flexible approach as required by the *Pearson* decision. The FDA could no longer censure all health claims on a determination that they may be misleading. Instead the FDA is now required to consider less restrictive approaches.<sup>78</sup> Agencies have been instructed that the paternalistic assumption that the public will use this information unwisely will not justify suppression.<sup>79</sup> *Pearson* instructs the FDA to recognize the consumer need to receive information.<sup>80</sup> Even after *Pearson*, the FDA remained conservative in its approach to health claims. In 2001, there were approximately seventeen approved health claims that could be used on food labels.<sup>81</sup> Each claim is authorized with model language to be used on the label and criteria that must be met in order for the food manufacturer to make the claim. One example of an approved health claim is for the connection between fruits and vegetables and cancer. The approved model claim is “Low-fat diets rich in fruits and vegetables (food that are low in fat and may contain dietary fiber, vitamin A or vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors.”<sup>82</sup> The criteria that must be satisfied are that that the food must actually be a fruit or vegetable, that it must be low in fat, and must be a good source (without fortification) of one of the following: vitamin A, vitamin C, or dietary fiber.<sup>83</sup>

In looking for the best solution to govern wine labels, it is important to consider how the FTC has dealt with health claims in the advertising of food. The FTC brought its policies up to date with the passage of the NLEA and the recognition that health claims provide the consumer with important information. One commentator has suggested that the FDA adopt an approach that more closely resembles that taken by the FTC.<sup>84</sup> The commentator argues that the FTC approach provides the necessary flexibility and effectiveness

---

<sup>77</sup>*Id.*

<sup>78</sup>Steinborn at 412.

<sup>79</sup>*Id.*

<sup>80</sup>*Id.* at 413.

<sup>81</sup>Ilene Ringel Heller, *Functional Foods: Regulatory and Marketing Developments*, 56 Food & Drug L.J. 197, Appendix (2001).

<sup>82</sup>*Id.*

<sup>83</sup>*Id.*

<sup>84</sup>Steinborn at 418-19.



required to properly regulate health claims.<sup>85</sup> The FTC issued a policy statement in 1994 that set out that health claims should be supported by “competent and reliable scientific evidence.”<sup>86</sup> This standard on occasion may allow health claims that would not otherwise be allowed by the FDA’s “significant scientific agreement” standard.<sup>87</sup> The FTC further defines the “competent and reliable scientific evidence” standard in the following manner: “test, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”<sup>88</sup> The FTC will rely on the FDA for the levels of fat, saturated fat, cholesterol, and sodium that will disqualify a food from including a health claim, but will not necessarily prohibit the advertising of health claims that do not meet these levels.<sup>89</sup> The guidelines do indicate that a failure to identify risk increasing factors may make the advertising claims deceptive and unacceptable. Although the FTC provides a more flexible approach, it does not have the experience or the scientific means to properly evaluate the claims made by food manufacturers. The FTC policy statement specifically mentions that it will rely on the FDA for several determinations. The FTC is concerned with protecting the consumer against fraud and deceptive advertising and not in protecting the health of the food consumer. Since the mission of these two agencies is vastly different it is important not to place too much emphasis on the benefits of the FTC approach. The FTC does provide greater access to the consumer, but since it does not thoroughly evaluate all claims made by food manufacturers it may be providing this information at too great a cost. There are studies that indicate that the FTC approach does strike the right balance. For example, FTC Bureau of Economics Staff Report conducted a study examining fat and cholesterol consumption from 1977 to 1990.<sup>90</sup> The study found

---

<sup>85</sup>*Id.* at 419.

<sup>86</sup>*Enforcement Policy Statement on Food Advertising*, <<http://www.ftc.gov/bcp/policystmt/ad-food.hitm>> \*9 (May 1994).

<sup>87</sup>*Id.*

<sup>88</sup>*Id.*

<sup>89</sup>*Id.* at \*11.

<sup>90</sup>Steinborn at 420.

that the relaxation of restrictions that allowed more diet-health claims on food added competitive pressure to food markets and led to reduced consumption of foods high in fat and cholesterol.<sup>91</sup> The evidence refuted the deceptive/confusion hypothesis that suggested the increased information to the consumer would lead to further deception in the marketplace and damage the consumer's diet.<sup>92</sup> The FTC provides another approach to regulate health claims on wine, but because the focus is on defrauding the consumer and not on the safety of the product this may not be the best approach to adopt.

After the passage of the NLEA health claims were permitted on food labels. Although at first the FDA was over conservative with the approval process of health claims, the current approach indicates that the FDA has adopted a more moderate attitude. After *Pearson v. Shalala*, the FDA was forced to recognize the benefit of providing information to the consumer and the right of food manufacturer's to disseminate information connecting diet and health benefits. Since the FDA must now attempt to achieve the least restrictive method for protecting the public against false health claims, it is possible to label foods with beneficial health claims and disclaimers. Some may argue that this approach still does not provide the necessary flexibility to get adequate information to the consumer; these critics fail to recognize that the FDA has a strong governmental interest in protecting the health of the public. The FTC approach allows too much freedom to food manufacturers and does not adequately protect the public. The current FDA approach is more effective. This approach should be expanded to incorporate wine and alcoholic beverages. The FDA has the experience and the scientific means to evaluate the health claims of wine that other agencies do not have. Before the FDA's control over wine labels can be further explored it is necessary to understand why health claims on wine labels are now an important concern. This can be done by evaluating the current research on the health effects of wine and other alcoholic beverages.

### **C. Current Research: The Health Effects of Wine**

---

<sup>91</sup>*Id.*

<sup>92</sup>*Id.*

The internet is full of information on the health benefits of wine and other alcoholic beverages. Some of the information represents scholarly research that has been done by scientists and experts in the field. Other information is disseminated by alcohol producers and other interest groups. What one can take away from almost all of these sources is that there is a U-shaped or J-shaped curve that represents the effects of alcohol consumption. In other words, moderate or light consumption of alcohol may be beneficial while heavier consumption can have extreme negative health consequences. Over the last ten years there has been significant research done on the positive health benefits of wine consumption. This research has changed the position of the alcoholic beverage industry on health effects on labels. Now that there may be a way for the industry to use health effects statements on labels to increase sales the ATF is being asked to reconsider the issue. It is important to examine the research that has been done in order to analyze the possibility of health effects statements on labels of wine and other alcoholic beverages.

In 1992, the Normative Aging Study reported on the U-shaped curve of alcohol consumption and mortality.<sup>93</sup> This prospective study examined the death rates from coronary heart disease. In 1973, 1823 men completed a drinking questionnaire. After twelve years 159 men died, 74 from coronary heart disease.<sup>94</sup> The results showed that moderate drinkers have lower death rates than both non-drinkers and heavy drinkers.<sup>95</sup> In 1997, the New England Journal of Medicine published another prospective study that began in 1982 with 490,000 men and women.<sup>96</sup> The Cancer Prevention Study II was made up of approximately 250,000 women and 238,000 men.<sup>97</sup> The participants were followed for nine years and 46,000 deaths resulted. The conclusion

---

<sup>93</sup>L.O. de Labry, R.J. Glynn, M.R. Levenson, J.A. Hermos, J.S. LoCastro and P.S. Vokonas, *Alcohol Consumption and Mortality in an American Male Population: Recovering the U-shaped Curve—Findings from the Normative Aging Study*. 53 J. Stud. Alcohol Jan 25 (1992).

<sup>94</sup>*Id.*

<sup>95</sup>*Id.*

<sup>96</sup>Michael J. Thun, M.D., Richard Peto F.R.S., Alan D. Lopez, Ph.D., Jane H. Monaco, M.S., S. Jane Henley, B.A., Clark W. Heath M.D. and Richard Doll F.R.S., *Alcohol Consumption and Mortality Among Middle-Aged and Elderly U.S. Adults*, 337 N. Eng. J. Med. 1705 (1997).

<sup>97</sup>*Id.*

was that in middle-aged and elderly populations, moderate alcohol consumption slightly reduced overall mortality, this benefit depended on a number of other risk factors.<sup>98</sup> As expected the death rate was significantly higher for those participants who reported at least four drinks daily. The causes of death included cirrhosis, alcohol related cancers, and external causes, such as accidents and suicide for men only.<sup>99</sup> The death rates from all cardiovascular disease was thirty to forty percent lower among both men and women who reported one drink daily.<sup>100</sup> The largest reduction in mortality rate from coronary heart disease was among those moderate drinkers who reported pre-existing heart disease or other risk of cardiovascular disease.<sup>101</sup> This article generated an editorial in the same issue titled the *Hazards and Benefits of Alcohol*.<sup>102</sup> The author of the editorial characterized alcohol *inter alia* as a “drug that contributes extensively to illness, violence, to social disorder, and mortality.”<sup>103</sup> The article focuses on the issues that the research does not answer such as whether those who have a high risk for cardiovascular disease might be even better off with diet and exercise, whether the non-drinkers reformed alcoholics, and whether the participants were honest about their alcohol consumption.<sup>104</sup> The editorial ends with the comment the alcohol industry is the only group to actually call for increased consumption.

Preliminary research focused on health effects in men, however, there were a number of studies that looked at the health effects of women. Evidence suggests that one of the negative effects unique to women is the increased incidence of breast cancer. In 1992, the American Journal of Epidemiology reported that there was an increased risk in breast cancer among postmenopausal women who consumed alcohol.<sup>105</sup> The study suggested that the link might be to the use of noncontraceptive estrogen as opposed to just alcohol and

---

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> John D. Potter, M.D., Ph.D., *Editorial: Hazards and Benefits of Alcohol*, 337 N.Eng. J. Med. 1763 (1997).

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> S.M. Gapstur, J.D. Potter, T.A. Sellers, A.R. Folsom, *Increased Risk of Breast Cancer with Alcohol Consumption in Postmenopausal Women*, 136 Am J. Epidemiol. 1221 (1992).

age.<sup>106</sup> In 1995, the New England Journal of Medicine published the results of a prospective study similar to that reported in 1992 for men.<sup>107</sup> The study concluded that light to moderate alcohol consumption in women was associated with lower death rate from cardiovascular disease and heavy drinking resulted in a higher death rate from other factors such as breast cancer and cirrhosis.<sup>108</sup> The study indicated that benefit was most apparent among women who were 50 years of age or older.<sup>109</sup> A study on women from age 25-42 indicated that there is unlikely to be a significant effect between alcohol and breast cancer among premenopausal women, but that a modest effect cannot be discounted.<sup>110</sup>

In 1999, the National Institute on Alcohol Abuse and Alcoholism published some interesting information in their Alcohol Alert.<sup>111</sup> What makes this information so noteworthy is that this organization has included the positive health benefits of moderate consumption in this volume of the alert. They reported that a review of epidemiological data from twenty countries indicated that there was a twenty to forty percent reduction in coronary heart disease in moderate drinkers compared to non-drinkers.<sup>112</sup> The report goes on to explore whether this is merely a connection or if alcohol causes this reduction. There is little data on whether the alcohol consumption of the moderate drinker is in fact an effect of alcohol or if the effect is due to a combination of healthy lifestyle choices.<sup>113</sup> The report also provides an explanation as to how alcohol consumption may work in the body to lower the risk of coronary heart disease. Heart disease, in the simplest form, is caused by the build up cholesterol and fatty substances on the wall of the coronary arteries. There is some animal laboratory evidence that indicates that alcohol may prevent arterial narrowing and reduce the

---

<sup>106</sup> *Id.*

<sup>107</sup> C.S. Fuchs, M.J. Colditz, G.A. Giovannucci, J.E. Manson, I. Kawachi, D.J. Hunter, S.E. Hankinson, C.H. Hennekens, and B. Rosner, *Alcohol Consumption and Mortality Among Women*, 332 N. Eng. J. Med. 1245 (1995).

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> M. Garland, D.J. Hunter, G.A. Colditz, D.L. Spiegelman, J.E. Manson, M.J. Stampfer, and W.C. Willett, *Alcohol Consumption in Relation to Breast Cancer Risk in a Cohort of United States Women 25-42 years of age*, 8 Cancer Epidemiol. Bio Prev. 1017 (1999).

<sup>111</sup> National Institute of Alcohol Abuse and Alcoholism, *Alcohol Alert* No. 45, <<http://www.niaa.nih.gov/publications/aa45.htm>> (October 1999).

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

possibility of clots forming that block the arteries and cause heart attacks.<sup>114</sup> This evidence is inconclusive at best and further research is needed to determine the impact that alcohol will have on humans. This study is attempting to explain the result of the previous studies that simply indicated a correlation between alcohol consumption and reduced incidence of coronary heart disease without providing a more in depth analysis. The latest indications on the benefits of alcohol point to the specific benefits of wine consumption. In December of 2001, Reuters reported that British researchers have presented findings that suggest that moderate consumption of red wine may lower the risk of heart disease.<sup>115</sup> The research suggests that polyphenols, which are found in the skins of grapes, decrease the production of proteins that contribute to the clogging of coronary arteries.<sup>116</sup> Red wine is made from the grapes with the skins on while white wine does not include the grape skin, and therefore not the high levels of polyphenols found in red wine. This research was done using cow artery's cells and therefore the human application is yet unknown.<sup>117</sup>

To counteract the numerous reports on the benefits of alcohol consumption the National Clearinghouse for Alcohol and Drug Information published an article entitled "What You Don't Know Can Harm You."<sup>118</sup> This article specifically addresses the negative effects of moderate consumption. None of the current research disputes that heavy drinking has negative health effects; instead it focuses on the benefits of moderate drinking. It is against this barrage of information that the National Clearinghouse felt it was necessary to point out the negative effects of moderate drinking. The article focuses on the low levels of drinking that will impair a person when driving.<sup>119</sup> Another effect that should be considered is the interaction with medication. The article also mentions that even moderate drinking can cause interpersonal problems, birth defects, and long term health effects.<sup>120</sup> The article is important because it refocuses the debate. The long term effects

---

<sup>114</sup>*Id.*

<sup>115</sup>Suzanne Rostler, *Study Suggest Why Red Wine Does a Heart Good*, Reuters, December 19,2001.

<sup>116</sup>*Id.*

<sup>117</sup>*Id.*

<sup>118</sup>The National Clearinghouse for Alcohol and Drug Information, *What You Don't Know Can Harm You*, NIH Publication No. 99-4323 (1999).

<sup>119</sup>*Id.*

<sup>120</sup>*Id.*

of alcohol may still be severe and alcoholism is a serious disease that many people face. The positive health effects need to be considered in relation to all of the negative health effects.

The research on alcohol consumption points to possible positive health benefits. This information should be understood within the greater context of the total impact of alcohol on the human body. The alcohol beverage industry is attempting to use this limited information to improve the public perception and the consumption of alcohol. Since this information is often times inconclusive or incomplete it is important that the consumer understand the full picture.

### **C. FDA Should Regulate Wine Labels**

In 1999, the BATF approved two additional statements for wine labels. These statements “...encourage you [the consumer] to consult your family doctor about the health effects of wine...” and direct consumers to send for the Dietary Guidelines for Americans to “...Learn the health effects of wine consumption...”<sup>121</sup> These statements allow the wine industry greater flexibility; however, they do not adequately address the issue. The BATF realizes that these measures are insufficient. The BATF’s limited response and the complexity of the research regarding the health effects of wine indicate that it is necessary to provide greater controls over wine labeling. The BATF does not have the resources or experience to properly regulate health claims regarding alcohol. The industry needs to be able to inform consumers of health effects in an accurate way. The BATF needs to change its policy toward health effects labeling on alcoholic beverages. Since the BATF has historically been influenced by the whim of the industry, the better approach is for Congress to revisit this issue and give control of alcohol beverage labeling to the FDA so that they can properly evaluate

---

<sup>121</sup> *Treasury Announces Actions Concerning Labeling of Alcoholic Beverages*, Treasury News RR-2937 February 5, 1999.

the health statements before they appear on the labels.

The BATF's history has showed that their policies are often influenced by the alcohol beverage industry. As previously discussed, in 1979 and 1981, the BATF attempted to promulgate regulations regarding ingredient labeling for alcohol. The industry lobby was so strong that these regulations were never put into effect. In *Center for Science in Public Interest v. Dept of Treasury*, the Court commented on how ingredient labeling decisions were made by conducting a cost-benefit analysis. This illustrates the way in which BATF makes decisions. Not necessarily a method that should be endorsed when considering health claims. In 1988, BATF finally approved health-related statements for which they drafted the language to be used and required the exact words to appear on the label. Now that the tide has turned and the labeling of alcohol may increase sales, the industry is lobbying the BATF again. This time they are in favor of labeling. The 1999 labeling regulations were a result of this lobby.<sup>122</sup> Again BATF determined the exact language that could be used on the label without giving the industry any flexibility or options. What is worse is that these statements are meaningless appeasement. They fail to provide the consumer with any information that may assist him or her in making an informed decision. In short, The BATF is too quick to change their mind under the pressure of the industry; and they should no longer be the gatekeeper for the claims on alcohol beverage labels.

In 1999, the BATF announced they would hold a public hearing on the health claims of alcohol to determine the proper use of labeling and advertising health effects.<sup>123</sup> The BATF invited comments on the proposal to permit balanced labels that were properly qualified, detailed, specific, and outlines the categories of persons for whom the positive effects would be outweighed by numerous effects. This proposal sets the bar very high for alcoholic beverage manufacturers. It does not allow them to make any health effects statements

---

<sup>122</sup>Erik Bierbauer, *Liquid Honesty: The First Amendment Right to Market the Health Benefits of Moderate Alcohol Consumption*, 74 N.Y.U. L. REV. 1057, 1059 (1999).

<sup>123</sup>“ATF Announces Public Hearings on Health Claims” ATF News <<http://www.atf.treas.gov/press/fy00press/120999health.htm>> (December 9, 1999).



unless they are specifically addressed to all classes of people who may not realize the health benefit. The practicality of this proposal leaves something to be desired. The proposal does not allow the industry to make truthful positive statements even in a limited sense unless accompanied by the complete list of negative effects. The BATF was attempting to strike a balance between the positive health effects and the negative effects; however, they did not strike the balance in the proper place.

Although the FDA has traditionally been even more paternalistic than the BATF, it is beneficial to consider the FDA use of the NLEA in health effects labeling on foods to provide a more adequate solution. Even the BATF recognizes that they may not be the best agency to evaluate the health effects and have stated that it will be necessary to consult with Health and Human Services to properly address the issue.<sup>124</sup> The NLEA provides an interesting framework to evaluate health effects labels. Although the NLEA originally required the approval of each and every health claim, currently, the manufacturer may include health claims for which they have significant scientific agreement. The FDA's ability to control labels was limited by *Pearson v. Shalala*. The Court in *Pearson* evaluated the regulations on labels of dietary supplements using the commercial speech three-part test. The first issue is whether the government's interest is substantial.<sup>125</sup> The next issue to consider is "whether the regulation directly advances the government interest asserted."<sup>126</sup> The third part of the test determines whether the fit between the government's means and the desired ends are reasonable.<sup>127</sup> The Court was skeptical of this paternalistic attitude and found that "disclaimers are constitutionally preferable to outright suppression."<sup>128</sup> The new approach of flexibility and finding the least restrictive way to protect the consumer is extremely applicable to the labeling of wine.

---

<sup>124</sup> *Treasury Announces Actions Concerning Labeling of Alcoholic Beverages*, Treasury News RR-2937 February 5, 1999.

<sup>125</sup> *Pearson*, 164 F.3d at 656.

<sup>126</sup> *Id.* (quoting *Central Hudson*, 447 U.S. 557, 566 (1980)).

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

The FDA has experience in creating standards for evidence in support of health claims. This experience can be adapted for use in the alcoholic beverage industry. In light of the recent developments regarding the health benefits of alcoholic beverages and more specifically wine it is necessary to reevaluate the labeling of these products. Labeling restrictions should be relaxed to better inform the consumer of the possible benefits. In doing so it is necessary to protect the consumer against false or misleading information. The FDA has the experience to do so and the NLEA illustrates that this agency is able to strike a balance between paternalism and consumer information.

## **VI. Conclusion**

The FAAA mandates that the BATF prevent any misleading information to appear on alcoholic beverage labels. The current state of the law extends way beyond that mandate, and disallows essentially all health-related information. The policy behind alcohol beverage labeling is more consistent with the FDA's mission to protect the consumer. Protection of the consumer should be afforded in a meaningful way that does not overreach the freedom of the manufacturer or the consumer. It is necessary to develop a workable standard that allows health claims to be evaluated for their legitimacy. Those claims that are supported by scientific evidence and will not mislead the consumer should be allowed to appear on the label. The FDA is better equipped to evaluate the scientific evidence and to determine if the claim is appropriate. The standard used by the NLEA is an appropriate solution for health claims on wine and other alcoholic beverage labels. The FDA can determine the least restrictive method to inform the consumer and protect them from harm.